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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,169	03/24/2004	Atsushi Sugiyama	SUGI3001D	4115

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/807,169	SUGIYAMA, ATSUSHI	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-23* is/are pending in the application.

4a) Of the above claim(s) *21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-20 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/926,138.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/2/04,3/29/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 10-23 are pending. Claims 10-20, 23 are considered on the merits. Claims 21, 22 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claims 21 and 22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 8/29/06.

The traversal is on the grounds that the groups do not have independent classification. This is not found persuasive because the inventions are classified in different subclasses and a search for a method is not necessarily coextensive with a search for a composition, particularly with regard to the literature searches. Please note, that if the method claims are found allowable, there is no rejoinder of the composition claims.

Specification

The disclosure is objected to because of the following informalities: the information in the first paragraph needs to be updated as the parent application has matured into an issued patent. Appropriate correction is required.

Claim Rejections - 35 USC § 112

INDEFINITE

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite because it cannot be understood if the three cleaning enzymes mentioned in the claim are added to the cleaning enzymes in the independent claim or if they replace all the cleaning enzymes in the independent claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 13, 14, 16-19 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Saegusa *et al.* [U] or Sugiyama *et al.* [V].

The claims are directed to a method of determining cAMP content in a sample comprising:
a) treating the sample with apyrase, alkaline phosphatase and adenosine deaminase,
b) converting cAMP to ATP,
c) converting ATP into F-6-P,
d) converting F-6-P into 6-phosphogluconolactone and NADPH,
e) determining the amount of NADPH without the use of radioactive agents.

The references are relied upon as explained below.

The references disclose the instantly claimed assay in Materials and Methods section of each.

Claims 10, 12-16, 19, 20, 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5,618,665 [AA].

US 5,618,665 discloses in example 10, a method of determining cAMP concentration in a sample comprising:

adding apyrase, alkaline phosphatase, adenosine deaminase to the sample, optionally adding glucose oxidase or glycogenphosphorylase to remove exogenous glycogen, converting cAMP into ATP, converting ATP in fructose-6-phosphate, converting F-6-P into 6-phosphogluconolactone and NADPH and determining the amount of NADPH. In Table 13, the PK reaction mixture contains myokinase and pyruvate kinase.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-16, 19, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,618,665 [A].

The claims and the reference have been discussed above.

Claim 11 is further directed to the use of glycogen phosphorylase, glucose oxidase and alkaline phosphatase to clean the sample.

The use of glucose oxidase, alkaline phosphatase and glycogen phosphorylase in combination to clean the sample would have been obvious because US 5,618,665 discloses the usefulness of all of these enzymes in a cleaning reaction. Thus, the use of any combination of these enzymes in a cleaning reaction is obvious because all have been taught to be individually useful.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,618,665 [A] as applied to claims 10-16, 19, 23 above, and further in view of Omburo *et al.* [AR] and Sawada *et al.* [AS].

The claims are further directed to the addition of a chelator to inactivate phosphodiesterase.

US 5,618,665 terminates the phosphodiesterase reaction by addition of base (col. 18, ls. 21-25) or by heating (col. 23, l. 6).

Omburo *et al.* teach that cAMP-phosphodiesterase (cGMP-inhibited phosphodiesterase) is inhibited by chelators such as EDTA (abstract).

Sawada *et al.* neither heats nor adds base to the mixture after the reaction with phosphodiesterase, but rater adds EDTA after completion of the phosphodiesterase catalysis of cAMP to AMP and production of F-6-P (page 92, part B). While Sawada *et al.* do no explain why the EDTA is added to the reaction mixture, the result would inherently be the inactivation of cAMP-phosphodiesterase which is known to be inhibited by chelators such as EDTA. Therefore, it would have been obvious to substitute the addition of EDTA to the reaction mixture for the heating or base addition taught in '665 when taken with Sawada *et al.* who adds EDTA to the reaction mixture and Omburo et al who disclose the cAMP-phosphodiesterase is inhibited by chelators.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due

to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651
September 15, 2006